AMENDMENTS TO THE SPECIFICATION

Please replace paragraph **[0005]** with the following amended paragraph:

[0005] Conventional syringes [each] include a barrel having an open proximal end and an opposed distal end. A cylindrical wall extends between the ends and defines a substance retaining chamber. [An elongate] A tip, [commonly] sometimes referred to as a luer, projects from the distal end of the syringe barrel and includes a narrow passage, which communicates with the substance-retaining chamber of the barrel. A plunger is [may be] inserted into the open proximal end of the syringe barrel for sliding fluid-tight engagement with the cylindrical chamber wall. Sliding movement of the plunger in a distal direction urges fluid in the chamber through the passage in the tip. Conversely, sliding movement of the plunger in a proximal direction draws fluid through the passage in the tip and into the chamber of the syringe barrel.

Please delete paragraph **[0006]** in its entirety.

Please replace paragraphs **[0007]** and **[0008]** with the following amended paragraphs:

[0007] Such syringes may further include a needle assembly with a needle cannula having a proximal end, a pointed distal end and a lumen extending axially therethrough. The needle assembly commonly includes a hub which is securable to [engageable with mounting means on] the syringe barrel for selectively placing the lumen of the needle cannula in fluid communication with the passage through the tip of the syringe barrel. The needle assembly may be removably or

fixedly mounted to the tip of the syringe barrel. [Alternatively, the needle cannula may be rigidly fixed or "staked" directly to the syringe barrel.]

[0008] Medications that are pre-filled into a syringe barrel must be sealed to prevent contamination or loss of the medication prior to use. Seals also prevent health care workers from being needlessly exposed to medications. Where a needle is not staked to the syringe body, the prior devices have included stoppers or closures mounted over the tip at the distal end of the syringe barrel, referred to as tip caps, to prevent leakage and to avoid contamination of the medication. When a pre-filled syringe is capped with a tip cap, it is especially important that a good seal be maintained. This is usually achieved by tightly affixing the tip cap to the syringe. However, when overly tightened the tip cap can be difficult to remove or may be damaged. Furthermore, a pre-filled syringe [is] may be autoclaved after filling and capping to ensure a sterile package for the contents. The autoclaving procedure however, can also have the side effect of interactions between the tip cap to the syringe, thereby further increasing the difficulty in removing the cap.

Please replace paragraph **[0010]** with the following amended paragraph:

[0010] Current tip caps used to seal the liquid opening of the syringe barrel, are typically a one-piece design having a circular [round] cap wall design. The mechanical advantage of a screw-type threaded cap is translation of a rotational force to an axial force, resulting in wedging the sealing mechanism of the tip cap onto the luer of the container, and forming a tight seal due

to the interference fit between the sealing mechanism and the luer. With the current tip caps, the torque required to attach and remove the tip cap [seal and unseal the bottle] is generated [at least partially by the friction created] when the user applies a gripping force to the outside of the cap [wall in order] to rotate the cap on and off the syringe.

Please replace paragraph **[0012]** with the following amended paragraph:

[0012] A need exists, therefore, for an improved syringe tip cap where the ability to attach and detach the tip cap is made easier by providing a tip cap that is easier to grip while simultaneously applying torque to rotate the tip cap. In particular, it would be advantageous to provide a tip cap with a non-circular[, for example elliptical,] shaped gripping surface that provides the user with a surface to grip the cap and apply force to the tip cap tangential to the axis of rotation without having to also apply a gripping force.

Please replace paragraph **[0031]** with the following amended paragraph:

[0031] Referring now to the drawings, FIG. 1 shows a tip cap according to the present invention. In particular, FIG.1 shows a tip cap 10. As can be seen, tip cap 10 includes a cap body 12 having a top wall 14 and a depending sealing base 16, and further includes [included] a shaft 18 for connecting to and disconnecting from a syringe 200. The shaft 18 and the cap body 12 form a single unitary tip cap for receiving a force imparted to the top wall 14 which causes the tip cap 10 to rotate and connect to a syringe body. The top wall 14 is a non-circular tubular structure, extending upwardly from the sealing base 16. The sealing base 16 is a substantially

flat surface having an upper surface [top] 16a defining a plane and lower surface [bottom] 16b [faces respectively]. Top wall 14 is rigidly joined to the upper surface [sealing base top] 16a, preferably about at least the majority of its perimeter, and the shaft 18 is rigidly joined to the lower surface [sealing base bottom] 16b.

Please replace paragraph **[0034]** with the following amended paragraph:

[0034] FIG. 4 depicts the tip cap 10 according to the present invention as viewed from the top (i.e., substantially perpendicular to the plane defined by the upper surface 16a). In this view, the substantially non-circularity of the top wall 14 is shown. Thus, a cross-sectional view taken along a plane that is substantially parallel to the plane defined by the upper surface 16a will be substantially con-circular. Preferably, the top wall 14 is elongated, having the major axis 40 and the minor axis 42. The top wall 14, according to the present invention, will preferably be formed in a non-circular elliptical shape, thereby providing an elongated gripping surface 50 defined by the top wall 14. The gripping surface 50 (see, e.g., FIG. 2) need not be limited to the surface defined along the major axis 40, but can include the surface defined along the minor axis 42. In addition, the gripping surface 50 may include a surface that extends along both the major and minor axes 40, 42. As will be described with reference to FIG. 9, the non-circular shaped top wall 14 allows a user to grasp the tip cap 10 and apply a rotational force (torque) to the tip cap 10, without having to simultaneously provide a tight grip on the tip cap 10. In addition, with the non-circular shaped top wall 14 of the present invention, the tip cap 10 is unable to roll away from a user, as is often the case with circularly shaped prior art tip caps.

Please replace paragraphs **[0040]** - **[0045]** with the following amended paragraphs:

[0040] Turning now to FIG. 8, there is shown a force diagram that illustrates the application of forces by a user to rotate a prior art cap about its central axis. FIG. 8 shows a circular top wall 80 of a prior art tip cap, with the rotational center point 82 (i.e., the intersection of the major and minor axes (which, for prior art devices are the same)) [having a central axis 82] and which is being grasped by a user's hand 84. User's hand 84 is shown exerting a gripping force 86, normal to the surface of the top wall 80. In order to rotate the cap the user must also apply a rotational force (torque) to the tip cap. For example, to rotate the tip cap in a clockwise direction, the user would apply force 88 tangential to the top wall 80. Likewise, to rotate the tip cap in a counterclockwise direction, the user would apply force 89 tangential to the top wall 80 axis of rotation. The amount of gripping force 86 the user must apply is proportional to the rotational force needed to turn the tip cap. For example, a user must grip the tip cap more tightly when turning a tip cap that has been tightly closed as opposed to a tip cap that has been less tightly closed.

[0041] In FIG. 9, there is shown a force diagram depicting the application of force by a user to rotate the tip cap 10 according to the present invention. FIG. 9 shows a top view of the tip cap 10 according to the present invention, depicting a non-circular top wall 14. [, having a central axis 90 and which is] being grasped by a user's hand 92. The rotational center point 90 (which is the intersection of the major and minor axes (which, for the present invention are

different)) is also shown. To rotate the cap in a counter clockwise direction, the user would apply forces 94 to the top wall 14. Likewise, to rotate the tip cap in a clockwise direction, the user would apply forces 96 to the top wall 14. In contrast to prior art designs, the user of the tip cap 10 according to the present invention merely applies a rotational force to the tip cap 10 to threadedly engage or disengage the tip cap; but a large gripping force is not required.

[0042] More particularly, a tip cap is opened or closed by imparting a force to the tip cap sufficient to overcome the forces holding it in place on the helical threads of the cap and the complementary container, or other complementary connection configuration, whereby the cap is moved from either an open or a closed position by the rotation of the cap. The forces to rotate the threaded cap are applied tangential to the axis of rotation of the cap at a distance from the axis of rotation. As shown and described in FIG. 8, in order to rotate a prior art circular [round] cap, it must be grasped with sufficient force to hold the cap, as well as rotate the cap about its central axis. Thus, force must be applied tangential to the axis of rotation to rotate the cap and normal to the cap surface to grasp and hold the cap. The force applied to hold the cap, is proportional to the rotational force applied thus making the application of both a gripping and rotating force more difficult, especially, for example when rotating a cap that is tightly affixed.

[0043] In contrast, the tip cap 10 according to the present invention, has an elongated gripping portion that provides the user with a lever arm to easily rotate the tip cap 10. Preferably, as depicted in FIG. 9, the user grasps the tip cap 10 at any points 98 on the top wall 14 a distance

"d" from the rotational center point [central axis] 90 as measured along the major axis 40. The forces 94 or 96 are [is] exerted directly on the top wall 14. The user need not grip the tip cap 10 to prevent slipping, because, unlike a circular tip [round] cap, the rotational forces (94 or 96) are [is] exerted normal to the top wall 14 at the points 98. The top wall 14 acts as a lever arm of length "d" to provide mechanical advantage to rotate the tip cap 10.

[0044] Rotational force may be used to remove the tip cap 10 even where a threaded connector is not provided for a syringe body. For example, the tip cap 10 can be twisted off of a luer to [onto] which it is mounted with a slip luer connection. The torque advantage described above, therefore, is as beneficial in this context, and similar contexts, as well.

[0045] The tip cap 10 of the invention may be made of a clear molded thermoplastic material so that the syringe tip may be readily viewed through the tip cap. Representative materials include, for example, polyethylene, polypropylene, and polyvinyl chloride. Although it is within the purview of the invention to provide tip caps which are transparent, it is also within the purview of this invention to provide tip caps which are color coded [for defining the kind of examination to be conducted on the specimen collected].

Please replace paragraphs **[0048]** - **[0050]** with the following amended paragraphs:

[0048] As will be recognized by one skilled in the art[.] and from the disclosure provided herein, various configurations are within the scope and spirit of the present [can be resorted to falling within the principles of the] invention [discussed above]. By way of non-limiting examples and turning to FIGS. 10a-f, alternate embodiments of the tip cap 10 according to the present invention are shown. FIG. 10a depicts an alternate embodiment wherein flanges 104 are positioned adjacent top wall 14 to provide the user with an enlarged gripping element, wherein the flanges extend outwardly from the top wall in a radial direction to the edge of sealing base 16. It should be noted however, that the dimension and size of the flanges can be varied to provide the user with a surface of sufficient size to apply force to rotate the tip cap. Preferable, the flanges 104 each have a radial length extending outwardly greater that their respective width extending in a circumferential direction. Furthermore, additional flanges 104 could be utilized in a further variation of the embodiment depicted in FIG. 10a. In addition, ribs 102 may also be provided with the embodiment of FIG. 10a, for providing an additional gripping element. [It should be noted that the radial distance from the center of the tip cap 10 to the edge of the flange 104 is greater than the radial distance to the edge of the rib 102.]

[0049] FIG. 10b depicts a further alternate embodiment of the present invention having two generally arcuate structures 108 protruding from sealing base 16 [being generally concave in shape]. The arcuate structures 108 are rigidly connected together by support 110 that also extends from sealing base 16. The structures 108 provide an easily gripped surface for the user to impart torque to the tip cap 10. As further seen in FIG. 10c, the shape and size of the arcuate

structures 108 can be varied to, for example, increase the size of the gripping surface. [It should be further noted that it would be apparent to one skilled in the art that the] The embodiments of FIGS. 10b and 10c do not have a receptacle shaped cap gripping surface. For this reason these embodiments resist the retention of moisture during a steam autoclave process. In addition, they have the added advantage of not being subject to a proclivity to nest one inside another when stored in bulk.

[0050] Turning now to FIG. 10d, a further alternate embodiment is depicted having a central structure 112 extending from sealing base 16, with a plurality of generally cylindrical structures 114 disposed about the central structure 112 at preferably ninety-degree intervals, for providing an easily gripped surface for the user to impart torque to the tip cap 10. FIG. 10d may be modified in accordance with the present invention by changing the number and spacing of [outer] structures 114. [, in] In addition while structures 112 and 114 are depicted as cylindrical, any other shape may be utilized, such as, for example, polygonal.